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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/014,338	12/10/2001	Herath Mudiyanselage Athula Chandrasiri Herath	9195-077	1523

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EXAMINER	
TURNER, SHARON L	
ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 10/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/014,338	HERATH ET AL.	
	Examiner	Art Unit	
	Sharon L. Turner	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 December 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-29* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Election/Restriction

1. Claims 1-29 are pending.

Improper Markush

2. Prior to setting forth the restriction requirement, it is pointed out that applicants have presented instant claims in improper Markush format, see Ex parte Markush, 1925 C.D. 126, In re Weber, 198 USPQ 334 and MPEP 803.02 and 806.04. The claims are improperly set forth as the genus claims encompassing multiple products, as identified and claimed, fail to share the characteristics of a genus, i.e., a common utility and a substantial structural feature essential to the disclosed utility. Alternatively, the claims define multiple structurally distinct compounds capable of different use, with different modes of operation, different function and different effects. A reference against one of the claimed components or methods would not be a reference against the other. Therefore, the restriction will be set forth for each of the various groups, irrespective of the improper format of the claims, because the claims define inventions which are not proper species.

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-3, 7-9, 24-26 in part drawn to polypeptides, classified for example in class 530, subclass 350.

II. Claims 4-6, 10-12 in part drawn to polynucleotide, classified for example in class 536, subclass 23.1.

III. Claim 13-15 in part drawn to a method of screening for and/or diagnosis with a peptide, classified for example in class 530, subclass 387.1.

IV. Claim 16 and 27 in part drawn to a method for prophylaxis and/or treatment with a

peptide, classified for example in class 514, subclass 2.

V. Claim 17 in part drawn to a method of screening for and/or diagnosis with a nucleic acid, classified for example in class 514, subclass 44.

VI. Claims 18 and 27 in part drawn to a method for the prophylaxis and/or treatment with a nucleic acid, classified for example in class 514, subclass 44.

VII. Claims 19-22 in part drawn to the extent of an antibody which binds specifically to a peptide, classified for example in class 530, subclass 387.1.

VIII. Claims 23 drawn to a method for the prophylaxis and/or treatment with an antibody, classified for example in class 424, subclass 130.1.

IX. Claim 28 in part drawn to a method of screening for compounds that modulate the expression of a polypeptide comprising determining the presence or absence and/or quantifying a polypeptide, classified for example in class 435, subclass 7.1.

X. Claim 28 in part drawn to a method of screening for compounds that modulate the expresssion of a polypeptide comprising determining the presence or absence and/or quantifying an antibody, classified for example in class 435, subclass 7.1.

XI. Claim 29 in part drawn to a method for monitoring/assessing a neurological or neuropsychiatric condition comprising determining the presence or absence and/or quantifying a polypeptide, classified for example in class 435, subclass 6.

XII. Claim 28 in part drawn to a method for monitoring/assessing a neurological or neuropsychiatric condition comprising determining the presence or absence and/or quantifying an antibody, classified for example in class 435, subclass 7.1.

4. The inventions are distinct, each from the other because of the following reasons:

5. Inventions I-II and VII are related as products. The products are distinct each from the other as the products are comprised of divergent structure, exhibit different effects and function; for example nucleic acids, peptides and antibodies.

6. Inventions III-VI and VIII-XII are related as processes. The processes are distinct each from the other as the processes differ in reagents, steps, functions and effects.

7. Inventions I-II, VII and III-VI, VIII-XII are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the processes for using the products as claimed can be practiced with another materially different product or (2) the products as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the processes for using the different nucleic acids, peptides and antibodies can be practiced with alternative nucleic acids, peptides and antibodies and the products as claimed can be used alternatively in a method of treatment, a method of making nucleic acids, peptides and antibodies, a method of screening compounds, and a method for detecting compositions.

8. Furthermore, in addition to the election of one of the above XII groups, further restriction is required under 35 U.S.C. 121 as set forth below to delineate the molecular embodiments to which the claims will be restricted in accordance with the elected group:

A) A single designated nucleic acid selected from SEQ ID NO's: 1 and 3.

B) A single polypeptide selected from SEQ ID NO's: 2 and 4.

C) A single designated antibody that specifically binds to the polypeptide selected from SEQ ID NO's: 2 and 4.

9. The inventions are distinct, each from the other because of the following reasons:

10. Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because the products indicated in groups A-C constitute patentably distinct inventions for the following reasons. Each of the polynucleotides, polypeptides and antibodies have a unique structural feature which requires a unique search of the prior art. The inventions indicated as A-C differ in structure and function as they are composed of divergent nucleic and amino acids and are differentially able to hybridize, bind or mediate biological functions. A reference to one element would not constitute a reference to another. In addition, searching all of the molecules in a single patent application would provide an undue search burden on the examiner and the USPTO's resources because the indicated searches are not co-extensive.

11. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

12. Because these inventions are distinct for the reasons given above and the search required for any Group is not required for any other Group, restriction for examination purposes as indicated is proper.

13. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

14. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). In order to be fully responsive, Applicant is required to elect a single group from

designated groups I-XII and a single molecular embodiment from each of designated groups A-C to which the claims will be restricted, even though the requirement is traversed. Applicant is advised that neither I-XII nor A-C are species election requirements; rather each of I-XII and A-C are restriction requirements. The subject matter for examination will be restricted to the extent of the subject matter of the elected groups. It is noted that while one of A-C may not be applicable to one of I-XII, applicant must elect one of each in order to be fully compliant.

15. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

16. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Turner, Ph.D. whose telephone number is (703) 308-0056. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 6:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached at (703) 308-4623.

Sharon L. Turner, Ph.D.
October 20, 2003